Meeting of the
Pharmacy and Therapeutics Committee
October 3, 2007
Draft Minutes

Members Present:
Randy Axelrod, M.D., Chair
Mark Oley, R. Ph., Vice Chair
Tim Jennings, R.Ph.
Avtar Dhillon, M.D.
James Reinhard, M.D.
Rachel M. Selby-Penczak, M.D.
Katherine Nichols, M.D.
Mariann Johnson, M.D.

Absent:
Renita Warren, Pharm.D.
Gill Abernathy, M.S., R.Ph.
Roy Beveridge, M.D.
Arthur Garson, M.D.
A quorum was present

Guests:
Manikoth Kurup, MD, Member, Board of Medical Assistance Services
88 representatives from pharmaceutical companies, providers, advocates, associations, etc.

DMAS Staff:
Patrick Finnerty, Agency Director
Cheryl Roberts, Deputy Director of Programs and Operations
Bryan Tomlinson, Director, Division of Health Care Services
Usha Koduru, Counsel to the Board, Office of the Attorney General
Keith Hayashi, R.Ph., Clinical Pharmacist
Katina Goodwyn, Pharmacy Contract Manager
Maryanne Paccione, Information Management Consultant

First Health Staff:
Debbie Moody, R.Ph, Clinical Manager, Virginia
Doug Brown, R.Ph, Director of Rebate Contracting Management
Sandy Kapur, Pharm.D, Rebate Support
Donna Johnson, R.Ph, Clinical Manager, Virginia

WELCOME AND INTRODUCTIONS FROM PATRICK FINNERTY, DMAS DIRECTOR

Patrick Finnerty welcomed the Committee to the meeting. He thanked the Committee members for the contribution of their time both through extensive preparation for the meeting and attendance. He noted his appreciation for their commitment of time and effort.

Mr. Finnerty informed the group of the six-month extension regarding the implementation of Tamper Resistant Prescription Pads for Medicaid enrollees. Congress recently enacted a law that mandates the use of tamper-resistant prescription pads for most non-electronic outpatient prescriptions written for fee-for-service Medicaid recipients, which was originally scheduled to become effective October 1, 2007. It will now become effective on April 1, 2008. He noted that Virginia Medicaid would comply with the implementation delay in accordance with this federal legislation to allow everyone time to prepare and comply.

Mr. Finnerty later reminded the Committee of the importance of completing and returning to DMAS the conflict of interest forms in their notebooks. This information is collected from the Committee at least annually to maintain on file with the agency.

COMMENTS AND WELCOME FROM DR. RANDY AXELROD, CHAIRMAN

Dr. Axelrod expanded on Mr. Finnerty's comments concerning the implementation of Tamper Resistant Prescription Pads. He raised the question of why the policy did not extend to everyone rather than limiting to the fee for service prescriptions and excluding Medicaid managed care plans.

Dr. Axelrod reviewed the agenda noting that there are 28 speakers, two new drug classes being reviewed for PDL eligibility, the annual phase I PDL review, and the review of the Draft Guidance Document for the Generic Drug Policy.

Dr. Axelrod introduced Usha Koduru, who is replacing Reatha Kay as the representative from the Office of the Attorney General.
Dr. Axelrod reviewed the guidelines for the presentations.

ACCEPTANCE OF MINUTES FROM April 17, 2007 MEETING
Dr. Axelrod asked if there were any corrections, additions, or deletions to the minutes from the April 17, 2007 meeting. With no comments, the minutes were accepted as written.

REVIEW OF DRAFT GUIDANCE DOCUMENT FOR THE GENERIC DRUG POLICY *(SEE DRAFT POLICY ATTACHED)*
Dr. Axelrod reminded the Committee that the goal of the policy is to achieve more timely capture of cost savings that result from the market introduction of less expensive, therapeutically equivalent generics in PDL-eligible drug classes. In addition, it will allow best pricing to be maintained during the exclusivity period until it is financially conducive to change to the generic.

Mark Oley noted that the intent, based on the discussion at the meeting on April 17, 2007, was to create a default policy for the management of new generics while maintaining the primary methods of reviewing new generics as a regular part of the P&T Committee process. Guidelines would be developed to allow the Department to take interim actions, in the absence of a P&T Committee discussion, which are in the best financial interest of the Commonwealth. First Health would make recommendations to the Department and information would be shared with the Committee at its next meeting. This new policy will only apply to PDL eligible classes.

Mr. Oley asked if anyone in attendance or on the Committee had a question or comment.

Dr. Nichols noted that the concepts of therapeutically equivalent and clinically equivalent are interchanged in the document. She requested that one term be used consistently throughout the document.

Dr. Axelrod asked the Committee and audience for other thoughts or comments.
With no other comments, Dr. Axelrod asked for a motion to accept the draft policy with the noted change.

Dr. Nichols made a motion to accept the draft policy; this motion was seconded and unanimously approved by the Committee.

Dr. Axelrod asked that the revised, final policy be reviewed at the next meeting.

Drug Class Reviews

To allow practicing physicians to return to their practices, Dr. Axelrod called speakers and reviewed classes in a different order than noted on the agenda.

Phase I PDL Annual Review: Central Nervous System- Other Sedative Hypnotics

George Bright, MD from Adolescent Health Center discussed Lunesta® (manufactured by Sepracor) Dr. Bright stated that he is not affiliated with the manufacturers of Lunesta®.
Dr. Bright treats two disease states in his practice: ADHD and Addiction**.**

Dr. Reinhard asked if any of the 60% of undiagnosed and unreported ADHD patients if many of them were on stimulants. Dr. Bright replied yes they were. Dr. Bright summarized information on this population that is being published.

Dr. Axelrod asked what was used to evaluate quality of life. Dr. Bright replied that they used domains of impairment to evaluate quality of life. Dr. Axelrod clarified that Dr. Bright and his team developed the domains of impairment as a way to measure quality of life.

Dr. Axelrod asked Dr. Bright to discuss the issue of adolescents self-medicating. Dr. Bright said that adolescents are consumed with peer group acceptance and plagued with social insecurity. To fit into the group and feel better, they self medicate with alcohol and marijuana. This social insecurity continues into adulthood and escalates into other drug additions.

Dr. Axelrod asked about the percent of ADHD patients with insomnia. Dr. Bright said that it was 70 to 80%.

Dr. Axelrod commented that his concern is the growing use of ADHD medications on college campuses and that an increase in sedative use may occur. Dr. Bright said that he has not seen this in his experience.

Husam Alathari, MD, Assistant Professor of Psychiatry from George Washington University discussed Rozerem® (Ramelteon/ manufactured made by Takeda) Dr. Alathari is on the speakers' board for Takeda. No questions or comments from the Committee.

David R. Spiegel, MD, Associate Professor of Clinical Psychiatry from Eastern Virginia Medical School discussed Rozerem® (Ramelteon/manufactured by Takeda) Dr. Spiegel is on the speakers' board for Takeda but is not being paid for this presentation.

Dr. Reinhard asked about increasing dosing if there is a benefit. Dr. Spiegel commented that there is no dose- related benefit or side effects with increased doses.

Dr. Axelrod asked about quantity limits or supply limits. Dr. Spiegel stated that there were no quantity or supply limits because there is no abuse potential.

Dr. Dhillon asked about drug interactions.Dr. Spiegel replied that fluvoxamine, a strong inhibitor CYP 1A2, does increase the bioavailability of Rozerem but side effects have not been seen.

Dr. Dhillon asked if smoking induced metabolism. Dr. Spiegel replied that there are no studies to support this theory.

MARK OLEY REVIEWED CENTRAL NERVOUS SYSTEM- BENZODIAZEPINE AND OTHER SEDATIVE HYPNOTICS
In this class, new generics for Ambien® (zolpidem) have entered the market.

Mark Oley motioned that Central Nervous System- Benzodiazepine and Other Sedative Hypnotics class be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Central Nervous System- Benzodiazepine and Other Sedative Hypnotics as PDL eligible.

Phase I PDL Annual Review: Cardiac Medications -- HMG CoA Reductase Inhibitors (Statins); Lipotropics Non-Statins: Fibric Acid; Omega3; Niacin Derivatives; and others.

John (Ian) Victor Nixon, M.B., Ch.B., M.D., F.A.C.C., Professor of Medicine (Cardiology)/ Director, Noninvasive Cardiology Services, Pauley Heart Station, Virginia Commonwealth University discussed Lipitor® (HMG CoA Reductase Inhibitors and Combinations/ Statins)
Dr. Nixon is a consultant for Pfizer as well as a speaker for Pfizer and many other companies.

Dr. Axelrod asked in the meta analysis review if the cut off was100. Dr. Nixon replied the goal of the meta analysis was to look at the aggressive therapy and side effects; therefore, the 100 mark was chosen because it was aggressive therapy.

Dr. Axelrod asked about the designated P value – a trend across LDL.
Dr. Nixon replied that this was an odd way to look at the data; it was a reverse look, a flat side effect profile.

Dr. Axelrod asked about the fact that the lower LDL levels did not follow the trends with CHF and other cardiac problems. Dr. Nixon replied that the question is where do we go with LDL levels. As the drugs get stronger, the LDL goes lower. The more aggressive you are the better the patient is. All of us could do better with lower LDL levels.

Dr. John M. Daniel, III, FACP, Richmond Internist, discussed Fenofibrates Tricor® and Niaspan ® (Lipotropics Non-Statins: Fibric, Niacin Derivatives)
Dr. Daniel noted that he has no conflicts of interest and he is a member of various P&T Committees.
No questions or comments from the Committee.

Margaret Savage, MD, MPH, Medical Science Liaison, Global Medical Affairs from Schering-Plough Corporation discussed Vytorin® and Zetia® (HMG CoA Reductase Inhibitors and Combinations/ Statins/ Lipotropics - CAI)
Dr. Axelrod asked if Zetia has anti-inflammatory properties.
Dr. Savage replied that if you use CRP as the anti-inflammatory marker of choice, Zetia alone does not have anti-inflammatory properties.

Phil Mendys, Pharm D, CPP, CLS, Director, Regional Medical Research Specialist for Pfizer discussed Atorvastatin/Lipitor® (HMG CoA Reductase Inhibitors and Combinations/ Statins)
Dr. Axelrod noted that Virginia Medicaid did not require a mandatory switch when the PDL was originally implemented. Recipients were allowed to continue their current treatment. Dr. Axelrod noted that the products are available and that the PDL is just a “preferred” drug list; non-preferred drugs may be obtained with authorization.

Ahmad Nessar, RPh, PharmD, Regional Scientific Manager for AstraZeneca discussed Crestor® (HMG CoA Reductase Inhibitors /Statins)
No questions or comments from the Committee.

Greg Auclair, M.Sc., Medical Science Liaison, Managed Markets for Reliant Pharmaceuticals discussed Lovaza™ / formerly Omacor) (Lipotropics – Omega 3)
No questions or comments from the Committee.
Dr. Axelrod asked about the fact that the drug was not indicated for hyperlypidemia of 200 to 499.
Mr. Auclair noted that while hyperlypidemia is defined as triglyceride levels greater than 200, the FDA did not give the indication. This is still in discussions with the FDA.

TIM JENNINGS REVIEWED CARDIAC MEDICATIONS HMG COA REDUCTASE INHIBITORS (STATINS)
There are a number of HMG-CoA reductase inhibitors on the market. Many of them have become available as generics. Simvastatin lowers LDL by 40 to 45 % range. Crestor, Lipitor, and Vytorin lower LDL by a range of 50 to 60% range.

TIM JENNINGS REVIEWED CARDIAC MEDICATIONS - LIPOTROPICS NON-STATINS: FIBRIC ACID

Fibric acids have been shown to reduce CV morbidity and mortality in both primary and secondary prevention trials. There are a number of them available on the market. The fibric acids should be considered as an alternative agent to the statins for specific lipid disorders or can be used as add-on therapy.

TIM JENNINGS REVIEWED CARDIAC MEDICATIONS - LIPOTROPICS NON-STATINS: OMEGA3

Omega-3-acid ethyl esters (Lovaza) reduce TG in patients with very high TG (>500 mg/dL). Several forms of omega-3 fatty acids are sold over-the-counter.

TIM JENNINGS REVIEWED CARDIAC MEDICATIONS - LIPOTROPICS NON-STATINS: NIACIN DERIVATIVES AND OTHER

Niacin has been shown to reduce major coronary events and, not to have significant flushes as per the P&T Chair. Compared to immediate release niacin, Niacin ER (Niaspan) was developed to increase compliance and reduce the incidence of flushing.

Tim Jennings motioned that Cardiac Medications HMG CoA Reductase Inhibitors and their combinations (Statins) continue to be PDL eligible. The motion was seconded. The Committee voted unanimously continue to consider Cardiac Medications HMG CoA Reductase Inhibitors (Statins) to be PDL eligible.

Tim Jennings motioned that Cardiac Medications Lipotropics Non-Statins: Fibric Acid continue to be PDL eligible. The motion was seconded. The Committee voted unanimously to continue to consider Cardiac Medications Lipotropics Non-Statins Fibric Acid to be PDL eligible.

Tim Jennings motioned that Cardiac Medications Lipotropics Non-Statins Omega3 continue to be PDL eligible. The motion was seconded. The Committee voted unanimously to continue to consider Cardiac Medications Lipotropics Non-Statins Omega3 to be PDL eligible.

Tim Jennings motioned that Cardiac Medications Lipotropics Non-Statins Niacin Derivatives and other continues to be PDL eligible. The motion was seconded. The Committee voted unanimously to continue to consider Cardiac Lipotropics Non-Statins Niacin Derivatives and others to be PDL eligible.

Phase I PDL Annual Review Angiotensin Receptor Blockers (ARBs)

Dr. Evette Johnson-Threat from Richmond Community Hospital, discussed Micardis®/HCT made by Boehringer Ingelheim Pharmaceuticals, Inc (Angiotensin Receptor Blockers (ARBs)

Dr. Johnson-Threat presented at the request of Boehringer Ingelheim Pharmaceuticals but is not being compensated. There were no questions from the Committee.

Dr. Selby-Penczak commented that once daily dosing is very important when evaluating a product.

Phase I PDL Annual Review (ACEs)

Dr. John Steinberg from the University of Maryland, Baltimore reviewed Altace® (Ace Inhibitors and Combinations)

Dr. Steinberg noted that he was compensated by King Pharmaceuticals to attend the meeting. There were no questions or comments from the Committee.

Pallav Raval, PharmD, MBA, Regional Associate Scientific Director from Novartis Pharmaceuticals Corporation discussed Tekturna (ACEs)

There were no questions or comments from the Committee.

MARK OLEY REVIEWED CARDIAC MEDICATIONS- ANGIOTENSIN RECEPTOR BLOCKERS (ARBS)

Exforge® manufactured by Novartis is a fixed-dose combination of the CCB, Norvasc® and the ARB, Diovan®. By complementary mechanisms, amlodipine and valsartan lower peripheral resistance, thereby lowering blood pressure. Exforge® is indicated for the treatment of hypertension. This fixed-dose combination is not indicated for the initial therapy of hypertension. Drug profiles are consistent with components.

MARK OLEY REVIEWED CARDIAC MEDICATIONS- ACE INHIBITORS

As everyone is aware, the ACE inhibitors affect the renin-angiotensin-aldosterone system. Tekturna® is a new in that it is a direct renin inhibitor, and directly targets the renin-angiotensin-aldosterone system (RAAS) at the point of activation by inhibiting renin and blocking the conversion of angiotensinogen to angiotensin I, leading to decreased plasma renin activity (PRA). Aliskiren (Tekturna®) is manufactured by Novartis and is available in 150-300 mg daily. This new drug has not been studied in patients less than 18 years old.

Both ACE inhibitors and Tekturna® are contraindicated in second and third trimesters of pregnancy; they are in Pregnancy Category C for the first trimester and class D in the second and third trimesters. Since Tekturna® is metabolized by CYP3A4, drug interactions are common with other drugs that are metabolized at this same site. Significant drug interactions can be seen when Tekturna® is given. The most commonly reported adverse event with Tekturna® was diarrhea.

There is a new generic moexipril/HCTZ for Uniretic® and the new generic amlodipine/benazepril for Lotrel®.

Mark Oley motioned that Cardiac Medications- ARBS be PDL eligible. The motion was seconded.
The Committee voted unanimously to consider Cardiac Medications- ARBS as PDL eligible.

Mark Oley motioned those Cardiac Medications- ACE Inhibitors be PDL eligible. The motion was seconded.
The Committee voted unanimously to consider Cardiac Medications- ACE Inhibitors as PDL eligible.

Phase I PDL Annual Review Nasal Steroids

Bonita Wilson, M.D, Board Certified Allergist discussed Veramyst® (manufactured by GlaxoSmithKline)

Dr. Wilson is on the speakers' board for Glaxo but is not being compensated for this presentation.

MARK OLEY REVIEWED NASAL STEROIDS

The new brand drug Veramyst™ (fluticasone furoate) is a corticosteroid nasal spray approved for the treatment of seasonal and perennial allergic rhinitis in adults and children (two years of age and older). Veramyst®, fluticasone furoate, is a new salt form of Flonase®, fluticasone propionate, a nasal spray indicated in children two years of age and older. Veramyst™ (fluticasone furoate) nasal spray is the first and only intranasal steroid (INS) proven to help relieve not only all four of the nasal symptoms, but also all three of the ocular symptoms (itching/burning, tearing/watering, redness). Veramyst® is administered once daily and offers a flexible dosing option based on patients 'symptom control.

Dr. Axelrod asked if there were any head-to-head studies comparing this to other similar products. The response was no.

Tim Jennings stated that the benefit of Veramyst® is the unique ergonomically designed nasal delivery device with a side actuator that releases a consistent.

Mark Oley motioned that Nasal Steroids be PDL eligible. The motion was seconded. The Committee voted unanimously to consider the Nasal Steroid class as PDL eligible.

Dr. Axelrod stated to the audience that the Committee appreciates the practicing physicians coming to speak at the meeting and he will continue to do his best to have them complete their presentation quickly. This is difficult with 29 speakers. Dr. Axelrod asked that the manufactures prepare their speakers for the time required for the meeting.

Phase I PDL Annual Review Phosphodiesterase 5 Inhibitor for PAH

Steven Nathan, MD, Medical Director, Lung Transplant & Advanced Lung Disease Program from Inova Fairfax Hospital discussed Revatio® (Sildenafil – manufactured by Pfizer)

Dr. Axelrod clarified that there are no criteria that prohibit the use of Revatio® once established that the recipient has PAH.

MARK OLEY REVIEWED CARDIAC MEDICATIONS-PHOSPHODIESTERASE 5 INHIBITOR FOR PULMONARY ARTERIAL HYPERTENSION
There is no change in this class for the Phosphodiesterase 5 Inhibitors. There are two new drugs with other mechanisms of action on the market; however, they are not categorized with this class as defined by the Virginia PDL.

Mark Oley motioned that Phosphodiesterase 5 Inhibitors be PDL eligible. The motion was seconded. The Committee voted unanimously to consider the Phosphodiesterase 5 Inhibitors class as PDL eligible.

Phase I PDL Annual Review of Urinary Antispasmodics

David Glazier, MD, Director, Virginia Urology Continence Center, reviewed Detrol® LA (manufactured by Pfizer)
Dr. Glazier is involved with pharmaceutical companies and is speaking on behalf of Pfizer but is not being financially compensated. There were no questions or comments from the Committee.

Michelle Mattox, Pharm.D, Director, Urology/Sexual Medicine from Pfizer Medical discussed Detrol LA
Dr. Axelrod asked the speaker to elaborate on the details of the head-to-head study in relation to the findings on primary outcome of incontinence micturatiuona and urgency. She replied that the study abstract looked at cognitive outcomes only.

MARK OLEY REVIEWED URINARY ANTISPASMODICS
Oxybutynin ER is a new generic for Ditropan® XL. Sanctura XR® (Trospium chloride) has a new extended release formulation made by Indevus Pharmaceuticals, Inc. The FDA approved new dosage form on August 3, 2007.

Mark Oley motioned that Urinary Antispasmodics be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Urinary Antispasmodics as PDL eligible.

New Drugs in PDL Phase II - Vyvanse®- Central Nervous System Stimulants/ADHD Medications

Dr. Salman Siddiqui, Board-certified Child and Adolescent Psychiatrist, discussed Vyvanse®
Dr. Siddiqui stated that he has no conflicts of interest. Dr. Nichols asked why prodrug makes such a difference. The presenter responded the drug levels are effective throughout the entire day and the patient exhibits less irritability as the levels of the drug decrease.

TIM JENNINGS REVIEWED ANTIHYPERKINESIS/CNS STIMULANTS
Concerta® and Adderall® XR are scheduled to become generic within the next year. This is probably the reason for making lisdexamfetamine (Vyvanse™) a prodrug. Lisdexamfetamine has duration of action of approximately ten to thirteen hours, which is comparable with the other drugs in the class. Currently, there is a substantial number of bid dosing with Adderall® XR. The benefit of the drug is that it is a prodrug.

Mr. Jennings asked for data requested at the last meeting from First Health Services Corporation. The response was that over a six-month period 1,500 distinct individuals were receiving a short acting as well as a long acting ADHD medication. More data will be obtained for the Committee. Mr. Jennings made the point that while these are once a day agents many times it requires two doses to allow the recipients to complete homework and get through the day.

Dr. Nichols asked if any head-to-head studies were conducted to evaluate this specific issue.
The manufacturer stated, yes, there is a head-to-head study that evaluated this.
Dr. Dhillon commented that the study referenced was too small (around 30 patients) and was a forced titration so it really did not address the question.

Dr. Axelrod would like to compare where Virginia stands with the percent of dual-therapy compared to mono-therapy against other First Health states. In addition, the research should address which states currently require Secure Paper (tamper resistant prescription pads), in particular the state of New York.

Tim Jennings motioned that Vyvanse™ be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Vyvanse™ as PDL eligible.

Review of Potential New Drug Classes - Growth Hormones

Anil Kumar, MD, Pediatric Endocrinologist, VCU Health System discussed Growth Hormones
Dr. Kumar is on the Pfizer speakers' board and he is actively enrolling his patients in a Pfizer Genotropin® study.

Dr. Axelrod stated that he understood that growth hormones could not be changed once started because of anti-body development. Dr. Axelrod asked if changing the carrier products created a problem. Dr. Kumar stated that while there are some antibodies that are developed, it is safe to change between products. All products are the same and they can be changed.

Dr. Axelrod asked if all pediatrician endocrinologists enrolled their patients in studies in the Commonwealth of Virginia. Dr. Kumar replied yes.

Dr. Axelrod asked if since all products are Somatropin, do physicians stick to prescribing certain name products only for the conditions with FDA approval or do they use products across diagnoses? Dr. Kumar stated that wide selections of products are necessary to allow the physician to enroll patients in the study so they can be monitored to get the most benefit. While all drugs work the same, physicians need to have choices to get the children in the best study for them to assure safety and benefits.

Mark Oley asked with safety and effectiveness in mind, when comparing idiopathic verses pathology do you chose one product over the other with a set of standards or do you base decisions on the individual patient? Dr. Kumar stated that he chose according to whom was doing research on the patient's condition. If he has ten kids with Turner's Syndrome, he enrolls them in the study that was doing research on Turner's Syndrome because they would be grouped with kids from all over the country with that same indication.

Mark Oley asked Dr. Kumar if he believed that all of the products work the same; however, the difference is the support group. Dr. Kumar stated, yes, this was correct.

Dr. Nichols asked if there was a clinical, patient-based criteria for choosing one product over the other. She continued to ask if it is more of how they fit into a study and the support that they will receive? Dr. Kumar said there are clinical, patient-based criteria for choosing one product over the other.

Dr. Axelrod clarified if the person has Turner's Syndrome they are entered into the study that reviews Turners Syndrome. Dr. Kumar replied that is correct.

Tim Jennings asked if there was financial compensation for participating with different registries. Dr. Kumar replied yes.

Tim Jennings asked if the compensation was different from registry to registry. Dr. Kumar replied yes. This discussion was ended to maintain financial review in the confidential financial meeting.

Donna King, PhD, Senior Regional and Medical Research Specialist, Endocrine Specialty Division, Pfizer Inc. discussed Genotropin®
There were no questions or comments from the Committee.

Kelly Behm, Pediatric Endocrinology Nurse, discussed Saizen® (manufactured by Serono)
Ms. Behm was presenting on behalf of Serono. There were no questions or comments from the Committee.

TIM JENNINGS REVIEWED GROWTH HORMONES AGENTS
There are a number of products available; however, none of them cover all of the indications. Many of the diagnoses have small populations that qualify as orphan drugs. One thing to consider is the potential for abuse and diversion for other uses of these products in this class. Diagnoses where growth hormones are indicated include Prader-Willi Syndrome (PWS), chronic renal insufficiency (CRI), Turner's syndrome, Idiopathic short stature (ISS), Short stature homeobox gene (SHOX), patients with HIV/AIDS typically experience cachexia, Short bowel syndrome (SBS), and Noonan Syndrome.

The differences in these products with respect to dosages and some adverse effects are a reflection of their various dosage forms and product packaging. These differences should be considered when evaluating these products.

Tim Jennings motioned that all of the Growth Hormones Agents be PDL eligible.
The motion was seconded. The Committee voted unanimously to consider Growth Hormones Agents as PDL eligible.

Potential New Drug Classes - Hepatitis C Treatment Agents

Thomas A. Parmelee, Pharm.D. Medical Science Liaison- Virology, Global Medical Affairs from Schering-Plough Corporation discussed, PegIntron®
Tim Jennings asked if they were studding the use in Hepatitis B. Dr. Parmelee said yes, there is published data on use in Hepatitis B; it is not indicated for Hepatitis B.

Dr. Axelrod asked for persistence and compliance rate for their product overall. Dr. Parmelee said that he did not have that information. He noted that it is a problem keeping people on the therapy and that is why they have the "be in change program" to support compliance and keep people on the program.

Dr. Axelrod asked if they had the statistics on the effectiveness of the "be in change program". The statistics were not available.

Dr. Axelrod noted that in his experience 30 % of recipients do not complete the first 12 weeks of therapy. On the other end, 25% of recipients are still on therapy after 12 weeks even though they are not EVR responders.

Donna E. Goldman, MD, Senior Medical Liaison – Virology, Board-certified Gastroenterologist from Roche discussed PEGASYS® (peginterferon alfa-2a) and COPEGUS®
Dr. Axelrod asked for persistence and compliance rate for their product overall. Dr. Goldman asked if he was referring to their dropout rate. There were no statistics available on this rate.

Dr. Axelrod asked what percent of patients are non-EVR at 12 weeks still receiving their drug and why would they support this. Dr. Goldman said that there is data on slow EVR responders. Recipients that respond between weeks 12 and week 24 are considered slow responders.

TIM JENNINGS REVIEWED HEPATITIS C TREATMENT AGENTS
There are two types of products, the older non-pegylated interferons and the newer Peginterferons that have longer half-lives and can be administered subcutaneously (SC) once weekly. These also have fewer side effects and are better tolerated. Ribavirin is generally generic.

Tim Jennings motioned that Hepatitis C Treatment Agents be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Hepatitis C Treatment Agents as PDL eligible.

Phase I PDL Annual Review of Beta Blockers

Kerry Cunningham, PharmD, Regional Medical Scientist GlaxoSmithKline, discussed Coreg CR
There were no questions or comments from the Committee.

TIM JENNINGS REVIEWED BETA BLOCKERS,
There are three new generics in this class: metoprolol succinate ER (new generic for Toprol XL®), Propranolol LA (new generic for Inderal® LA) and carvedilol (new generic for Coreg®). Within this class is Zebeta®, Toprol XL®, Coreg®, and Coreg CR® all have clinical data to support their use in the management of heart failure; however, only Toprol XL® and Coreg® are FDA-approved for it.

Mark Oley motioned that Beta Blocker Agents be PDL eligible. The motion was seconded.
The Committee voted unanimously to consider Beta Blocker Agents as PDL eligible.

Phase I PDL Annual Review of Calcium Channel Blockers

MARK OLEY REVIEWED CALCIUM CHANNEL BLOCKERS
There is a new generic for Norvasc® and Lotrel®, Amlodipine.

Mark Oley motioned that Calcium Channel Blockers Agents continue to be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Calcium Channel Blockers Agents as PDL eligible.

Phase I PDL Annual Review of Gastrointestinal - Proton Pump Inhibitors (PPIs)

MARK OLEY REVIEWED GASTROINTESTINAL - PROTON PUMP INHIBITORS (PPIS)
Prevacid® has a new dosage form that is a suspension.

Mark Oley motioned that Gastrointestinal - Proton Pump Inhibitors (PPIs) Agents continue to be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Gastrointestinal - Proton Pump Inhibitors (PPI) Agents as PDL eligible.

Phase I PDL Annual Review of Gastrointestinal Histamine 2 Receptor Antagonists (H-2RA)

MARK OLEY REVIEWED GASTROINTESTINAL - HISTAMINE 2 RECEPTOR ANTAGONISTS (H-2RA)
There were no significant changes in this class to address.

Mark Oley motioned that Gastrointestinal - Histamine 2 Receptor Antagonists (H-2RA) Agents continue to be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Gastrointestinal - 2 Receptor Antagonists (H-2RA) Agents as PDL eligible.

Phase I PDL Annual Review of Electrolyte Depleters

MARK OLEY REVIEWED ELECTROLYTE DEPLETERS
There were no significant changes in this class to address.

Mark Oley motioned that Electrolyte Depleters Agents continue to be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Electrolyte Depleters Agents as PDL eligible.

Phase I PDL Annual Review of Topical Immunomodulators

Mark Oley reviewed Topical Immunomodulators
There were no significant changes in this class to address. Both products in this class have a black box warning regarding the long-term safety of topical calcineurin inhibitors, which has not been established.

Mark Oley motioned that Topical Immunomodulators Agents continue to be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Topical Immunomodulators Agents as PDL eligible.

Phase I PDL Annual Review of Asthma and Allergy classes

Paul Prince, Senior Regional Scientific Manager, from AstraZeneca discussed Symbicort® and Pulmicort® Flexhaler
Dr. Axelrod asked if there were outcomes from the change to the Flexhaler. Mr. Prince said, yes, they have outcomes; they are the same or slightly less than the outcomes as with the Turbohaler™.

MARK OLEY REVIEWED ASTHMA AND ALLERGY

The National Asthma Education and Prevention Program (NAEPP) issued comprehensive updates to their clinical guidelines for the diagnosis and management of asthma -- The Expert Panel Report 3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma. The new guidelines for asthma management focus on four main areas: Assessment and Monitoring' Patient Education, Control of Environmental and Other Exacerbating Factors and Medications. He highlighted the findings related to Medications for the Committee.

- The most effective medications are those with anti-inflammatory effects.
- Classes for long-term control include corticosteroids, cromolyn sodium and nedocromil, immunomodulators, leukotriene modifiers, and long-acting bronchodilators (LABAs): salmeterol and formoterol.
- LABAs should not be used as monotherapy for long-term control.
- In adolescents older than 12 years, adults, and children older than 5 years with moderate persistent asthma, LABA is the preferred therapy in combination with inhaled corticosteroids.
- LABAs are not recommended for acute exacerbations.
- Sustained-release theophylline is an alternative, not a preferred adjunctive therapy with inhaled corticosteroids.
- Short-acting bronchodilators (i.e., SABAs) are the therapy of choice for acute symptoms and exercise-induced asthma; anticholinergics are an alternative.
- Systemic corticosteroids are used as adjunct to SABAs to prevent recurrence and speed recovery.

MARK OLEY REVIEWED INHALED CORTICOSTEROIDS

Symbicort® is a new combination agent made by AstraZeneca it is a combination product of budesonide, a Corticosteroids, and formoterol fumarate dehydrate, a long acting beta agonist. Inhalation Aerosol is a controller medicine for people aged 12 years and older for the long-term maintenance treatment of asthma. Pulmicort Flexhaler™ is a new dosage form for Pulmicort®; it is also available as a powder.

Mark Oley motioned that Inhaled Corticosteroids be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Inhaled Corticosteroids as PDL eligible.

Cristine Sproles, PharmD., Account Director for Sepracor discussed Brovana™ (Anticholinergics for COPD) and Xopenex®, Xopenex® HFA (Beta Adrenergics)

There were no questions or comments from the Committee.

TIM JENNINGS REVIEWED BETA-2 ADRENERGICS

Perforomist® (Formoterol fumarate) is a long-acting beta-2 agonist inhalation solution for nebulization approved for long-term, twice daily maintenance treatment of bronchoconstriction for chronic obstructive pulmonary disease (COPD). Manufactured by Dey Pharmaceuticals, the FDA has approved a new dosage form of Formoterol that had previously been available as a dry powder formulation (Foradil®).

Tim Jennings motioned that beta-2 agonist be PDL eligible. The motion was seconded. The Committee voted unanimously to consider beta-2 agonist as PDL eligible.

TIM JENNINGS REVIEWED COPD ANTICHOLINERGICS

There were no significant changes in this class to address.

Tim Jennings motioned that COPD Anticholinergics be PDL eligible. The motion was seconded. The Committee voted unanimously to consider COPD Anticholinergics as PDL eligible.

MARK OLEY REVIEWED SECOND GENERATION ANTIHISTAMINES (LSAs)
There were no significant changes in this class to address. There is a new drug, Xyzal®, manufactured by UCB and Sanofi-Aventis.

Mark Oley motioned that Second Generation Antihistamines (LSAs) be PDL eligible.
The motion was seconded. The Committee voted unanimously to consider Second Generation Antihistamines (LSAS) as PDL eligible.

New Drugs in PDL Phase II

TIM JENNINGS REVIEWED ONYCHOMYCOSIS ORAL ANTIFUNGALS
A new generic for Lamisil®, Terbinafine, is now available on the market.

Tim Jennings motioned that Terbinafine be PDL eligible. The motion was seconded.
The Committee voted unanimously to consider Terbinafine as PDL eligible.

TIM JENNINGS REVIEWED CEPHALOSPORINS
Two new generics are now available: Cefprozil (generic for Cefzil®) and Cefdinir (generic for Omnicef®). The manufacturer removed Lorabid from the US market in 2007.

Tim Jennings motioned that Cefdinir and Cefprozil be PDL eligible. The motion was seconded.
The Committee voted unanimously to consider Cefdinir and Cefprozil as PDL eligible.

COMMENTS FROM OFFICE OF THE ATTORNEY GENERAL
Ms. Usha Koduru from the Attorney General's office stated that under the Virginia Freedom of Information Act (FOIA), specifically Virginia Code section 2.2-3711, a public body such as the P&T Committee, may go into a closed session for any of the 33 reasons listed in that statute. The discussion of manufacturer and wholesaler prices is not one of the 33 reasons listed.

She stated the Attorney General strongly supports the principles of open government embodied by the FOIA and believes in the opportunity of the Commonwealth's citizens to witness the operation of government to the fullest extent.

Federal Law 42 U.S.C. 1396r-8(b)(3)(D) requires such pricing information to be kept confidential. On this point, federal law supersedes the Virginia FOIA. Since the P&T Committee must discuss this pricing information as part of its duties, pursuant to federal law a confidential meeting must occur for the consideration of this pricing information she cautioned only this confidential information should be discussed.

Mark Oley made a motion for the P&T Committee to resume the meeting in another room to discuss this confidential information regarding prices charged by the manufacturers and wholesalers of the drug classes discussed at this P&T Committee meeting. This confidential meeting is authorized by Federal Law at 42 U.S.C. § 1396r-8(b) (3) (D) that requires this information to be kept confidential.

This motion was seconded and unanimously approved by the Committee.

The meeting adjourned to an executive session.

The Committee returned to the room.

Mark Oley confirmed that to the best of each of the Committee member's knowledge the only information discussed at the confidential meeting was information regarding prices charged by the manufacturers and wholesalers of the drug classes discussed at this P&T Committee meeting. As authorized by Federal Law at 42 U.S.C. § 1396r-8(b) (3) (D) that requires this information to be kept confidential.

Phase I PDL Annual Review ~ PDL status changes and new class additions effective January 1, 2008 unless otherwise noted

Mark Oley made the motion to maintain the current PDL with only the following changes in the Asthma and Allergy ~ Nasal Steroids class: add Fluticasone Propionate as preferred and make Flonase® non-preferred. The motion included making the generic Fluticasone Propionate preferred effective today, 10/03/07. The motion was seconded and the Committee voted unanimously to make the stated changes.

Mark Oley made the motion to maintain the current PDL with only the following changes in the Cardiac Medications ~ HMG CoA Reductase Inhibitors (Statins) class: add Pravastatin Sodium as preferred and make Pravachol® non-preferred. The motion was seconded and the Committee voted unanimously to make the stated changes.

Mark Oley made the motion to maintain the current PDL with only the following changes in the Genitourinary Urinary Tract Antispasmodics class: make both Ditropan XL® and oxybutynin chloride ER non-preferred. The motion was seconded and the Committee voted unanimously to make the stated changes.

Mark Oley made the motion to maintain the current PDL with only the following changes in the Central Nervous System ~Benzodiazepine Sedative Hypnotics and Other Sedative Hypnotics classes: add to preferred Zolpidem and move Restoril® 7.5 mg capsule to non-preferred. The motion included making the generic Zolpidem preferred effective today 10/03/07. The motion was seconded and the Committee voted unanimously to make the stated changes.

Mark Oley made the motion to maintain the current PDL with only the following change in the Asthma and Allergy ~ COPD Anticholinergics class: add Ipratropium Bromide Solution as preferred and move Duoneb® to non-preferred (*its generic Ipratropium Bromide / Albuterol Nebs will remain non-preferred*). The motion was seconded and the Committee voted unanimously to make the stated changes.

Mark Oley made a motion to maintain the current PDL with only the following change in the Cardiac Medications ~ Beta Blockers class: Coreg will be non-preferred and carvedilol will be preferred. The motion included making the generic carvedilol preferred effective today, 10/03/07. With the motion seconded, the Committee voted unanimously to maintain the current PDL Cardiac Medications ~ Beta Blockers class (including Beta Blockers Diuretic Combination) with the noted change.

Mark Oley made a motion to maintain the current PDL CNS Stimulant/Antihyperkinesis class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL CNS Stimulant/Antihyperkinesis class with no change. The new drug Vyvanse® will be non-preferred.

Mark Oley made a motion to add the following products as preferred to the Hepatitis C Treatment Agents class: Pegasys® Conv.Pack, Pegasys®, Peg-Intron® and Peg-Intron® Redipen. With the motion seconded, the Committee voted unanimously to approve the preferred products in the PDL Hepatitis C Treatment Agents class as read. All other drugs in this class will be non-preferred.

Mark Oley made a motion to add the following products as preferred to Growth Hormones class: Genotropin®, Norditropin® Cartridge, Nutropin® Aq Cartridge, Nutropin®, Nutropin® Aq Vial, and Norditropin® Nordiflex. With the motion seconded, the Committee voted unanimously to approve the preferred products in the PDL Growth Hormones class as read. All other drugs in this class will be non-preferred.

Mark Oley made the motion to make a change in the Oral Antifungals for Onychomycosis class to add Terbinafine Hydrochloride as preferred effective today, 10/03/07. The motion was seconded and the Committee voted unanimously to make the stated changes.

Mark Oley made motions to maintain the current PDL status with no change in the classes listed below. With the motion seconded, the Committee voted unanimously to maintain as current with no change for all of the following classes:

- Asthma and Allergy ~ Beta Adrenergics including Beta Adrenergics long acting agents and Inhaled Beta Adrenergics Nebs
- Asthma and Allergy ~ Second Generation Antihistamines (LSAs)
- Asthma and Allergy ~ Inhaled Corticosteroids including Inhaled Corticosteroids/ Beta Adrenergics
- Asthma and Allergy ~ Second Generation Antihistamines (LSAs)
- Cardiac Medications ~ Angiotensin Receptor Blockers (ARBs) including ARBs with diuretics
- Cardiac Medications ~ Angiotensin Converting Enzyme Inhibitors (ACE Inhibitors) including ACE/ARB Combination and ACE Combination
- Cardiac Medications ~ Lipotropics Non-Statins: Fibric Acid including Omega 3 -- Triglyceride lowering agent products
- Cardiac Medications ~ Calcium Channel Blockers including Combination HBM and Calcium Channel Blocker
- Cardiac Medications ~ HMG CoA Reductase Inhibitors (high potency statins) including Lipotropics Non-Statins: CAI
- Cardiac Medications ~ Lipotropics Non-Statins: Niacin Derivatives
- Cardiac Medications ~ Phosphodiesterase 5 Inhibitor for Pulmonary Arterial Hypertension
- Gastrointestinal ~ Proton Pump Inhibitors (PPIs)
- Gastrointestinal ~ Histamine 2 Receptor Antagonists (H-2RA)
- Topical Immunomodulators
- Electrolyte Depleters

Criteria Discussion for Growth Hormones

A motion was made to accept the criteria as written with the future addition of criteria for Idiopathic ISS. The motion was seconded and the Committee voted unanimously to accept the criteria as written with the future addition of criteria for Idiopathic ISS.

Criteria Discussion for Hepatitis C Treatment Agents

A motion was made to accept the criteria as written with the future addition of criteria describing the monitoring for Non-EVR responders and related continuation/discontinuation of therapy. The motion was seconded and the Committee voted unanimously to accept the criteria as written with a future addition of criteria describing the monitoring for Non-EVR responders and related continuation/discontinuation of therapy.

Criteria Discussion of Phase II New Drugs

A motion was made to accept the PDL criteria as written for phase II PDL classes with new drugs with no changes. With the motion seconded, the Committee voted unanimously to accept the PDL criteria as written for phase II new drugs with no change.

Criteria Discussion of Phase I Annual Review

A motion was made to accept the criteria as written with the addition of criteria as described below:

1) The First Health Clinical Call Center requests the following change in the Gastrointestinal Histamine 2 Receptor class:
   - Treatment of warts is not an FDA approved diagnosis or indication for Tagamet / cimetadine and a PA will not be approved for this diagnosis or indication.

2) Add criteria to the Lipotropics added to Fibric acid derivatives & Omega 3 Agent-
   - If documented very high triglycerides of (≥ 500 mg/dL) in adult patients. Then a PA for Omacor®/Lovaza® can be approved with out any specific preferred medication trials.

With the motion seconded, the Committee voted unanimously to accept the PDL criteria for phase I drug classes as written with the changes noted above.

Dr. Axelrod reviewed plans for the next meeting in the Spring of 2008.
The meeting was adjourned.

ATTACHMENT

Pharmacy and Therapeutics Committee
DRAFT Guidance Document Regarding New Generic Drug Policy
for the Preferred Drug List

Introduction

The Virginia Medicaid Pharmacy and Therapeutics (P&T) Committee, in its meeting on April 17, 2007, requested the development of a Guidance Document to address the management of generic drugs in classes subject to the Preferred Drug List (PDL). Of interest to the Committee was clarifying the conditions in which a new generic drug would be adopted as "preferred" on the PDL; particularly when immediate action is warranted and there are 30 days or more until the next scheduled P&T Committee meeting. The intent was to create a default policy for the management of new generics while maintaining the primary methods of reviewing new generics as a regular part of the P&T Committee meeting agenda. Optimally, the P&T Committee will review pending generics and act upon all new generics during annual drug class reviews. A motion was made and unanimously approved to create a Guidance Document to develop a policy to address this issue.

One recommendation was to utilize price points as a method of determining when generic drugs should be considered for preferred status on the PDL. In addition, the Committee's discussion included the potential removal of brand name drugs from preferred status when clinically equivalent generic drugs are more cost effective. This Guidance Document outlines current policies and proposed guidelines for the future management of new generics in drug classes subject to the PDL.

Objective

The goal of the policy is to achieve more timely capture of cost savings that result from the market introduction of less expensive, therapeutically equivalent generics in PDL-eligible drug classes. Guidelines will be developed to allow the Department to take interim actions, in the absence of a P&T Committee discussion, which are in the best financial interest of the Commonwealth. The policy will not address clinical issues where health and safety concerns are present because all drugs involved are therapeutically equivalent. This policy recognizes that the PDL is mature and the most significant changes now relate to the introduction new generics in established PDL-eligible drug classes.

Current New Drug Policies

Since its inception, the P&T Committee has adhered to policies for reviewing new drugs in therapeutic classes subject to the PDL as well as a specific new generic drug policy (See "Preferred Drug List Generic Policy" and "Process for Reviewing New Drugs" at the following link: http://www.dmas.virginia.gov/pharm-p&t_committee.htm). Under the current policy, as the Food and Drug Administration (FDA) approves a new drug product in a class previously reviewed and deemed "PDL-eligible" by the P&T Committee, the drug is immediately considered non-preferred and requires prior authorization. Further determination of the drug's status is typically conducted by the P&T Committee at its next meeting; however, current guidelines allow the Department's Director to change new generics to preferred, in consultation with the P&T Committee Chair, if he chooses, where drugs are clinically equivalent and cost information warrants this change. This process includes a review of supplemental rebate contracts to ensure there are no conflicts as well as appropriate notification to P&T Committee members and public stakeholders.

Item 302 S.2.b (Chapter 847) of the 2007 General Assembly Appropriations Act requires that the P&T Committee schedule meetings at least quarterly to review any drug in a class subject to the PDL that is newly approved by the FDA, provided there is at least thirty (30) days notice of approval prior to the quarterly meeting. First Health Services Corporation (FHSC) monitors all new drugs (brand and generic) in PDL-eligible classes introduced in the market through weekly updates from First DataBank (FDB) and notifies the

Department of changes. A drug will be considered eligible for P&T Committee review if it meets one of the following criteria:

- A "new brand" drug defined by the FDA as having the new drug application (NDA) approved which indicates that the product may be marketed in the United States
- A "new brand of an established generic" and has met the FDA definition above of "new brand"
- A "First Generic" on the monthly FDA update of "Generic Drug Approvals". First Generics are those drug products that have not previously been approved as generic drug products and are new to the marketplace.

Drugs that meet these criteria are included on the agenda of the next P&T Committee meeting for review, regardless of whether an annual review is conducted for the respective drug class. New, non-branded generic drugs within a drug class previously evaluated by the P&T Committee are deemed the same PDL status (preferred or non-preferred) as the existing generic drugs in the related class and therefore, will be addressed at the next annual review of the class.

FHSC makes recommendations for the PDL status of the drug based on the determination of its potential "cost advantage". The "cost advantage" is currently determined by the final net cost, which is the cost to the Commonwealth net of all federal (CMS) and supplemental rebates. When comparing the final net cost of the generic to the brand, the lesser cost determines which drug presents the greatest "cost advantage". At the point the cost difference of the generic is neutral or in the best interest of the Department, a recommendation is made to change the status of the generic to preferred along with the brand. With the P&T Committee's next annual review of the class, it may also be recommended to change the brand to non-preferred.

The new generic drug policy will be integrated with existing policies to clarify interim actions in the absence of a P&T Committee discussion.

Recommendations for Future Management of New Generic Drugs on PDL

The following changes or clarifications are recommended to the current new drug policies when brand drug A is preferred and a new generic of drug A is released to the market or scheduled for release to the market:

Procedural Change/ Clarification

1. A "new generic watch list" will be established and updated on an ongoing basis with all new generics in PDL-eligible classes as they enter the market or are anticipated (with FDA-approval). This will include both first time generics as well as multi- source generics that affect the marketplace. On a quarterly basis, the "new generic watch list" will be sent via e-mail to the Department, P&T Committee Chair and another P&T Committee member. This document will contain the PDL class name; the generic and brand names; the current PDL status of both the brand and generic; information on Federal Upper Limit (FUL) or Maximum Allowable Cost (MAC) price, if they exist; summary of financial comparison; number of manufacturers; recommendations for PDL action; and other pertinent information. Also sent quarterly will be an updated PDL criteria showing all brands and generics as well as their PDL status. A generic watch list or update will be sent on an ad-hoc basis if pricing changes dictate that more immediate review and action are required by the Department.
2. Within two weeks of the new generic drug's pricing information being posted to First DataBank, Virginia Medicaid's drug database, FHSC will evaluate the financial impact; the final net cost (drug cost minus all rebates) of preferred brand A will be compared to the final net cost of generic A. This pricing evaluation of new generic drugs will include consideration of the current FUL and MAC pricing, if they exist. *The publishing of the generic price on FDB is an indication that the generic is widely available in the market.* This information will be included on generic watch list and sent on a quarterly or ad hoc basis to the Department, P&T Committee Chair, and another P&T Committee member.

3. All supplemental rebate contract addendums proposed by manufacturers must be thoroughly reviewed to ensure there are no provisions in conflict with this policy.
4. The PDL Quicklist and criteria will be updated and posted to the DMAS and FHSC web sites within a week of any decisions made by the Department's Director, who may consult with the P&T Committee Chair or another member of the P&T Committee, outside of a P&T Committee meeting.

Decision-Making Changes/ Clarification

1. FHSC will advise of the product with the best cost advantage to the Department. At the time the generic and brand drugs are equivalent in final net cost, then the generic drug will be recommended to become preferred and the brand drug non-preferred. *This is recommended because the generic typically begins to be reimbursed at the MAC or FUL once the generic price becomes equivalent to the brand; these pricing methodologies commonly create the lowest price.* FHSC will consider the financial impact on supplemental rebate collections before recommending a brand agent be removed from preferred status on the PDL.
2. If there is a need for immediate action, the Department's Director may consult with the P&T Committee Chair or another Committee member to determine the status of new generics in PDL eligible classes. Immediate action will be necessary if there are 30 days or greater until the next P&T Committee meeting and there is widespread market availability of the new generic. FHSC's recommendations, based on the guidelines above, will be provided for consideration of the drug status. DMAS staff will develop a "decision brief" summarizing the relevant information. Unless there are exceptional circumstances, the guidelines will be applied automatically (systems change to prior authorization requirements) with the approval by the Department's Director. Any actions taken outside of P&T Committee meetings by the Director will be communicated to members via email messages and during their next scheduled meeting.
3. Any decision to change the status of the preferred brand to non-preferred outside of P&T Committee meetings will be made by the Department's Director in consultation with the P&T Committee Chair or another Committee member. DMAS staff will develop a "decision brief" summarizing the relevant information. Any actions taken by the Department's Director in consultation with the P&T Committee Chair or another Committee member, outside of P&T Committee meetings, will be communicated to members via email messages and during their next scheduled meeting. In addition, the brand drug manufacturer will be notified of the change.
4. All new generics to be reviewed by the P&T Committee will be included on the agenda of its next meeting. FHSC will present an updated "generic watch list" to review market information and recommendations for new generics. The clinical discussion of the new generic drugs will occur in the public meeting; there should be little discussion as these drugs are clinically equivalent to the brand already established on the PDL. During the confidential session of the meeting, all of the financial information for each new generic along with the current PDL status of the related brand and generic products will be reviewed. The Committee will determine the PDL status of the brand and generic drug products as with current practices.

Review by the P&T Committee

All other components of existing new drug policies will remain and these new actions will be integrated into these policies to clarify interim actions in the absence of a P&T Committee discussion. The revised policy will be reviewed by the P&T Committee during an upcoming meeting and published on the DMAS web site. Information on these policy changes may also be included in the next *Medicaid Memorandum* to medical and pharmacy providers that addresses PDL updates.